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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DUNSTON, JENNIFER ANN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/784,004	SAH ET AL.	
	Examiner	Art Unit	
	Jennifer Dunston	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-66 are pending in the instant action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 (as they read on the nucleic acid), drawn to a method of identifying a surrogate marker of neuropathic pain in a mammal, comprising determining an amount of at lest one nucleic acid, classified in class 435, subclass 6.

II. Claims 1-6 (as they read on the protein) drawn to a method of identifying a surrogate marker of neuropathic pain in a mammal, comprising determining an amount of at least one protein, classified in class 435, subclass 7.1.

III- CCCX. Claims 11-12, drawn to a method of evaluating the level of neuropathic pain in a mammal, comprising determining the amount of at least one nucleic acid being a surrogate marker of neuropathic pain, wherein the nucleic acid comprises a nonredundant sequence of one of SEQ ID NO: 1-308, respectively, classified in class 435, subclass 6.

CCCXI - CDLXX. Claims 16-17, drawn to a method of evaluating the level of neuropathic pain in a mammal, comprising determining the amount of at least one nucleic acid being a surrogate marker of neuropathic pain, wherein the nucleic acid comprises a nonredundant sequence of one of SEQ ID NO: 471-630, respectively, classified in class 435, subclass 6.

CDLXXI - DCXXXII. Claims 13-14, drawn to a method of evaluating the level of neuropathic pain in a mammal, comprising determining the amount of at least one protein being a surrogate marker of neuropathic pain, wherein the protein comprises a nonredundant sequence of one of SEQ ID NO: 309-470, respectively, classified in class 435, subclass 7.1.

DCXXXIII - DCCXCII. Claims 18-19, drawn to a method of evaluating the level of neuropathic pain in a mammal, comprising determining the amount of at least one protein being a surrogate marker of neuropathic pain, wherein the protein comprises a nonredundant sequence of one of SEQ ID NO: 631-790, respectively, classified in class 435, subclass 7.1.

DCCXCIII- DCCCXCIX. Claims 27-28 and 59-66, drawn to a method of evaluating the effect of a compound or composition on the level of neuropathic pain in a mammal, comprising determining an amount of at least one nucleic acid in a tissue extract of a skin biopsy, wherein the nucleic acid comprises a nonredundant subsequence of one of SEQ ID NO: 791-897, respectively, classified in class 435, subclass 6.

DCCCXCI- CMLXVI. Claims 32-33, drawn to a method of evaluating the effect of a compound or composition on the level of neuropathic pain in a mammal, comprising determining an amount of at least one nucleic acid in a tissue extract of a skin biopsy, wherein the nucleic acid comprises a nonredundant subsequence of one of SEQ ID NO: 963-1038, respectively, classified in class 435, subclass 6.

CMLXVII-MXXXI. Claims 29-30, drawn to a method of evaluating the effect of a compound or composition on the level of neuropathic pain in a mammal, comprising determining an amount of at least one protein in a tissue extract of a skin biopsy, wherein the protein comprises a nonredundant subsequence of one of SEQ ID NO: 898-962, respectively, classified in class 435, subclass 7.1.

MXXXII-MCVII. Claims 34-35, drawn to a method of evaluating the effect of a compound or composition on the level of neuropathic pain in a mammal, comprising determining an amount of at least one protein in a tissue extract of a skin biopsy, wherein the protein comprises a nonredundant subsequence of one of SEQ ID NO: 1039-1114, respectively, classified in class 435, subclass 7.1.

MCVIII. Claims 37-41 (as they read on the nucleic acid), drawn to a method of identifying a biomarker of biological activity of a neurotrophic agent, comprising determining an amount of at least one nucleic acid, classified in class 435, subclass 6.

MCIX. Claims 37-41 (as they read on the protein), drawn to a method of identifying a biomarker of biological activity of a neurotrophic agent, comprising determining an amount of at least one nucleic acid, classified in class 435, subclass 7.1.

MCX- MCLVIII. Claims 49-50, drawn to a method of evaluating in vivo biological activity of a neurotrophic agent, comprising determining an amount of at least one nucleic acid, wherein the nucleic acid comprises a nonredundant subsequence of one of SEQ ID NO: 1115-1163, respectively, classified in class 435, subclass 6.

MCLIX- MCLXXXVII. Claims 54-55, drawn to a method of evaluating in vivo biological activity of a neurotrophic agent, comprising determining an amount of at least one nucleic acid, wherein the nucleic acid comprises a nonredundant subsequence of one of SEQ ID NO: 1179-1207, respectively, classified in class 435, subclass 6.

MCLXXXVIII-MCCII. Claims 51-52, drawn to a method of evaluating in vivo biological activity of a neurotrophic agent, comprising determining an amount of at least one protein, wherein the protein comprises a nonredundant subsequence of one of SEQ ID NO: 1164-1178, respectively, classified in class 435, subclass 7.1.

MCCIII-MCCXXXI. Claims 56-57, drawn to a method of evaluating in vivo biological activity of a neurotrophic agent, comprising determining an amount of at least one protein, wherein the protein comprises a nonredundant subsequence of one of SEQ ID NO: 1208-1236, respectively, classified in class 435, subclass 7.1.

Claims 7-10 and 15 link(s) inventions of Groups III- DCCXCII. Claim 20 links those inventions within Groups III- DCCXCII that are drawn to muscle-specific markers. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 7-10 and 15. The restriction requirement between the linked muscle-specific inventions is **subject to** the nonallowance of the linking claim, claim 20. Upon the election of one of Groups III- DCCXCII, Applicant must indicate if the elected sequence is a muscle-specific sequence.

Claims 31-26 and 31 link(s) inventions of Groups DCCXCIII - MCVII. Claim 36 links those inventions within Groups DCCXCIII - MCVII that are drawn to muscle-specific markers. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 31-26 and 31. The restriction requirement between the linked muscle-specific inventions is **subject to** the nonallowance of the linking claim, claim 36. Upon the election of one of Groups DCCXCIII - MCVII, Applicant must indicate if the elected sequence is a muscle-specific sequence.

Claims 42-48 and 53 link(s) inventions of Groups MCVIII- MCCXXXI. Claim 58 links those inventions within Groups MCVIII- MCCXXXI that are drawn to muscle-specific markers. The restriction requirement between the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 42-48 and 53. The restriction requirement between the linked muscle-specific inventions is **subject to** the nonallowance of the linking claim, claim 58. Upon the election of one of Groups MCVIII- MCCXXXI, Applicant must indicate if the elected sequence is a muscle-specific sequence.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I- MCCXXXI are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups I- MCCXXXI comprise steps which are not required for or present in the methods of the other groups in that each group requires steps to identify distinct groups of nucleic acid molecules (I and MCVIII), steps to identify distinct groups of proteins (II and MCIX), detect distinct nucleic acid molecules (III-CDLXX, DCCXCIII-CMLXVI and MCX-MCLXXXVII), or detect distinct proteins (CDLXXI-DCCXCII, CMLXVII-MCVII and MCLXXXVIII-MCCXXXI). The end results of the methods are different: identifying a surrogate nucleic acid marker for neuropathic pain (I), identifying a surrogate protein parker for neuropathic pain (II), evaluating the level of neuropathic pain in a mammal based upon the results obtained with a distinct nucleic acid (III-CDLXX) or protein (CDLXXI-DCCXCII), evaluating the effect of a compound or composition on the level of neuropathic pain in a mammal based upon the results obtained with a distinct nucleic acid (DCCXCIII-CMLXVI) or protein (CMLXVII-MCVII), identifying a nucleic acid biomarker of biological activity of a neurotrophic agent (MCVIII), identifying a protein

biomarker of biological activity of a neurotrophic agent (MCIX), and evaluating the in vivo biological activity of a neurotrophic activity based upon the results obtained with a distinct nucleic acid (MCX-MCLXXXVII) or protein (MCLXXXVIII-MCCXXXI). Thus, the operation, function and effects of these different methods are different and distinct from each other. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification. For those groups with the same classification, there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02). Each method requires a separate search of the patent and non-patent literature to identify steps not shared with any other group. Furthermore, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and Examiner time for reviewing the computer search results. Accordingly, the inventions of Groups I- MCCXXXI are distinct from each other and the searches are not coextensive for any of the groups. The additional searching required to search more than one group would impose a serious search burden, and thus restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

jad

CELINE QIAN, PH.D.
PRIMARY EXAMINER